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March 22, 2016

U.S. ex rel. Bilotta v. Novartis Pharm. Corp.  
No. 11 Civ. 0071 (PGG)

Dear Judge Gardephe:

We represent defendant Novartis Pharmaceuticals Corporation (“NPC”) in the above-referenced action. We respectfully submit this letter, pursuant to Part 4A of Your Honor’s Individual Rules of Practice and Local Civil Rule 37.2, to request a pre-motion conference in connection with NPC’s anticipated motion for a protective order. NPC seeks an order protecting it from discovery relating to 72,870 additional promotional programs that fall outside a protocol that the parties spent months negotiating and jointly described to the Court in advance of our November 12 status conference.

A. Background

The Government alleges that NPC used “sham” speaker programs (devoid of legitimate medical, educational or promotional discussion or content regarding the NPC drugs) to provide unlawful kickbacks to healthcare practitioners (“HCPs”) in violation of the Anti-Kickback Statute and the False Claims Act. The Government’s operative 2013 Complaint—which was filed following a nearly two-year investigation—identifies 269 purportedly “sham” events. Nevertheless, the Government served sweeping document requests on NPC, demanding, among other things, the production of “[a]ll documents concerning each Speaker Program on the Covered Drugs” conducted during the relevant time period. (9/20/2013 Gov’t’s First Set of Requests for Documents and Interrogatories, Doc. Req. No. 8.) That request spanned roughly a decade, and encompassed tens of thousands of NPC events. Indeed, the Government acknowledged at the parties’ first meet and confer that the request would unduly burden NPC and, at NPC’s request, agreed to identify the specific events at issue for which plaintiffs wanted discovery.

The parties then spent approximately nine months negotiating the specific parameters of that agreement (which we referred to as the “protocol”), including by participating

in numerous meet and confer sessions, exchanging dozens of substantive emails and conducting detailed analyses of the burdens involved under various discovery proposals. The parties ultimately settled on a discovery protocol, designed to provide NPC's complete response to the Government's document requests, that was comprised of two components: (1) "general" discovery;<sup>1</sup> and (2) "event-specific" discovery. With respect to events, the parties ultimately agreed that the Government could identify and obtain discovery for an unspecified number of events, so long as those events were conducted by no more than 150 NPC sales representatives.<sup>2</sup>

In advance of the November 12, 2015 Court conference, the parties jointly wrote to the Court and described the two-pronged approach to discovery, as set forth above.

See Dkt. No 134, Nov. 10, 2015 Ltr. from P. Bharara to Hon. Paul G. Gardephe at 2-3. That letter makes no reference to discovery or events beyond those identified by the parties' protocol. In fact, at that time, the discovery protocol discussed in the parties' letter was the exclusive discovery, and consequent definition of the universe of events at issue, of which we were aware. Based on that protocol, NPC and the Government jointly represented to the Court that the parties could complete fact discovery by July 29, 2016. See Dkt. No 134 at 3. The Court ordered the parties to do so, cautioning that there would be no further extensions of that deadline. See Dkt. No. 137, Pre-Trial Conference Transcript at 3:13-16. But unknown to NPC (and presumably to the Court), the Government intended to expand dramatically the scope of this case, rendering the negotiated discovery protocol meaningless, and making it impossible for the parties to meet the July 29 fact discovery deadline.

Only fifteen days after the Court conference—on November 27, 2015—the Government supplemented answers to interrogatories that had been served by NPC more than two years before (in September 2013) to suddenly allege that 79,236 NPC promotional programs were "fraudulent or resulted in a kickback". The Government then demanded discovery for each of those 79,236 events, even though those events were organized by more than 5,400 NPC sales representatives—far more than the 150 sales representatives to which the parties had agreed—and fall well outside the protocol that the parties negotiated and jointly described to the Court.

The Government's interrogatory response not only exploded the size of this case, but it also reflected a fundamental shift in the Government's allegations. Up until that point, the Government's case (and, consequently, the parties' discovery discussions) had focused on speaker programs—a type of NPC promotional event in which an HCP "speaker" presents NPC-

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<sup>1</sup> NPC agreed to conduct "general" discovery by applying numerous and detailed agreed-upon search terms to the electronic files of hundreds of NPC employee custodians, including both headquarters and field sales force personnel.

<sup>2</sup> The agreed-upon protocol would provide the Government with extremely broad discovery, especially when coupled with the 2.5 million pages of documents already produced to the Government during the investigation phase of this case. Among other things, the discovery protocol requires NPC to search the files of more than 300 custodians; apply thousands of individual search terms to its data; and review tens of millions of pages of documents. That protocol will also include discovery of approximately 6,400 events conducted by up to 150 sales representatives.

approved material to other HCPs. The Government's Complaint centers around speaker programs (indeed, all but 7 of the 269 events described in the Complaint are speaker programs); and the parties' event-specific discovery protocol similarly revolves around speaker programs.<sup>3</sup> Nevertheless, more than 64% of the events identified in the Government's interrogatory response—that is, more than 50,000 of the newly-alleged "sham" events—are roundtables, a different type of promotional program that does not involve an HCP "speaker".

On December 22, 2015, NPC served eight interrogatories, asking the Government to provide, among other things, the factual basis for its belief that each of the 79,236 newly identified events was "fraudulent or resulted in a kickback". A month later—on January 25, 2016—the Government served its Objections and Responses, which failed to include a single substantive response to any of NPC's interrogatories. Following a meet and confer on February 9, the Government agreed to supplement its response to two of NPC's eight interrogatories in order to provide (among other things) "the factual bases" for the Government's identification of the 79,236 allegedly "sham" events. Given the discovery schedule and the unexpected effort dramatically to expand the case, NPC asked the Government to do so promptly, but the Government took another month—until March 11—to provide its supplemental response. That supplemental response sets forth one or more of nine purported "factual bases" for each of the 79,236 allegedly "sham" events.<sup>4</sup>

At the same time that it served its supplemental interrogatory response, the Government offered to "compromise" on its request for discovery pertaining to the 79,236 allegedly "sham" events (72,870 of which fall outside the agreed-upon protocol). Specifically, the Government offered to modify its request to include: (1) the production of certain categories of "back-up" discovery found in discrete locations within NPC's files (e.g., specific CDs of event receipts and certain financial documents), as well as all slide decks and reports of investigations that NPC could locate pursuant to a specified search; and (2) either (a) a stipulation that NPC would not challenge the Government's use of NPC's events databases to establish the truth of the information contained therein and would agree to how the parties would interpret that data, or (b) the production of additional items of "back-up" discovery for 25,000

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<sup>3</sup> For example, the event-specific discovery protocol requires NPC to apply, as search terms, (1) the last name of each speaker program speaker, and (2) a search term derived from the title of each speaker program topic to be presented—concepts that are inapplicable to promotional programs that are not speaker-led.

<sup>4</sup> Those "factual bases" are: (1) "[t]he event was attended by one or more healthcare providers who had attended events on the same or a substantially similar topic multiple times"; (2) "[t]he event was predominantly social in nature and/or served no legitimate educational purpose for some or all of the participants"; (3) "[t]here were an inappropriate number of attendees at the event"; (4) "[t]he amount spent on meals and beverages was excessive"; (5) "[t]he speaker was paid for an event that did not take place"; (6) "[t]he event took place on a weekend"; (7) "[i]nappropriate honoraria was paid in connection with the event"; (8) "[t]he number of attendees was falsely inflated in the speaker program data"; and (9) "[t]he event took place at a venue that was not modest or conducive to a legitimate educational event".

events. If NPC did not so agree, the Government reserved its right to request complete “back-up” discovery for all 79,236 events. NPC rejected that proposal.

NPC now seeks a protective order, requiring the Government to abide by the parties’ agreed-upon protocol and confining the Government to the events and discovery identified under it.

#### **B. Motion for a Protective Order**

The impropriety of the Government’s discovery request is highlighted by the Government’s March 11 supplemental interrogatory response. As set forth in that response, the Government identified tens of thousands of allegedly “sham” events by applying nine arbitrary criteria (or “markers”) to NPC’s events databases.<sup>5</sup> The vast majority of those criteria, however, reveal absolutely nothing about whether a legitimate promotional event took place, particularly in the context of non-speaker-led events such as roundtables. For example, the Government’s criteria (which largely repeat the allegations of the Complaint) include that “[t]he event took place on a weekend” and “[t]he amount spent on meals and beverages was excessive”. These “markers” do not establish what did (or did not) happen at an event—let alone that the event was a “sham”, “fraudulent” or intended to be a “kickback”. Yet the Government has used these criteria to justify expansive discovery, spanning approximately half of all of the speaker programs and roundtables conducted during the relevant time period.

The Government is already receiving far more event-specific material than it could ever present to a jury.<sup>6</sup> Applying the parties’ negotiated event-specific protocol, the Government has put at issue—and will receive discovery relating to—approximately 6,400 individual events—more than 23 times the number of events alleged in the Complaint. Having had years to investigate its claims, there is simply no need for the Government to identify events, or to obtain discovery relating to events, beyond that. For that reason alone, NPC is entitled to a protective order. See, e.g., Fed. R. Civ. P. 26(b)(1) (discovery must be “proportional to the needs of the case” and courts must consider, *inter alia*, “whether the burden or expense of the proposed discovery outweighs its likely benefit”); Fed. R. Civ. P. 26(b)(2)(C)(i) (“[T]he court must limit the . . . extent of discovery . . . if . . . the discovery sought is unreasonably cumulative or duplicative.”); Henry v. Morgan’s Hotel Grp., Inc., No. 15 Civ. 1789, 2016 WL 303114, at \*3 (S.D.N.Y. Jan. 25, 2016) (noting that amended Rule 26(b)(1) “is intended to encourage judges to be more aggressive in identifying and discouraging discovery overuse by emphasizing the need to analyze proportionality before ordering production”).

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<sup>5</sup> In the event the Government denies that is the case, NPC respectfully requests that the Court compel the Government to provide more complete responses to NPC’s second set of interrogatories, to supplement the purported “factual bases” the Government provided on March 11, and to identify accurately the methodology the Government has applied to select the allegedly “sham” events.

<sup>6</sup> We briefly address below, under “The Government’s Approach to Trial”, our request to discuss at the upcoming status conference set for April 7, whether the Government’s use of “markers” is a viable way to prove its case, in any event.

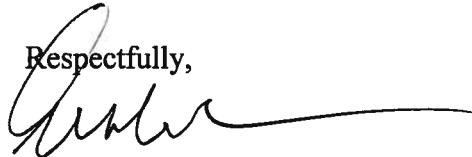
Finally, the event-specific discovery that the Government has requested would be extraordinarily burdensome for NPC to provide. As NPC has explained to the Government on numerous occasions—including at the parties’ earliest meet and confers—the “back-up” material that the Government seeks is not compiled in any one place. To even try to locate the requested information for 79,236 events, tens of thousands of which occurred more than ten years ago, NPC would (among other things) have to load, process and search the files of more than 5,400 individual sales representatives. The parties negotiated the protocol precisely so that NPC would not have to do that. NPC should be protected from the Government’s excessive and burdensome request. See, e.g., Vaigasi v. Solow Mgmt. Corp., No. 11 Civ. 5088, 2016 WL 616386, at \*13, \*15, \*24-25 (S.D.N.Y. Feb. 16, 2016).

### C. The Government’s Approach to Trial

As will be set forth in more detail in NPC’s status letter in advance of the pre-trial conference, the Government’s March 11 supplemental interrogatory response also raises broader concerns about how the Government intends to prove its case at trial.

The Government plainly cannot (and apparently does not intend to) offer individualized proof for 79,236 events at trial—let alone present detailed proof for every prescription written by the more than 108,000 HCPs who appear to have attended any of those programs. Consequently, NPC is concerned that the Government intends to use the “markers” it apparently applied to NPC’s events databases as a substitute for direct evidence at trial. As we hope to address at the April 7 status conference, and will describe more fully in our upcoming status letter to the Court, we believe that such a novel and unprecedented approach to proving liability is improper and would result in a violation of NPC’s due process rights.

Respectfully,



Evan R. Chesler

Hon. Paul G. Gardephe  
United States District Judge  
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VIA ECF

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